VPULSE™ System

Users Manual

COTHERA

Healing Engineered™

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FOR A DEMO
SCAN QR CODE
WITH YOUR
SMART PHONE

Welcome to the VPULSE™ System. Dedicated to providing state-of-the-art therapeutic products, Cothera manufactures and markets durable medical devices used to prevent the occurrence of venous thrombosis and accelerate recovery by treating acute pain from post-orthopedic surgery. Please read this instruction manual completely prior to using the system to ensure reliable and safe operation.

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Introduction

The Cothera VPULSE™ is a patent-pending technology which provides a unique combination of rehabilitative therapies:

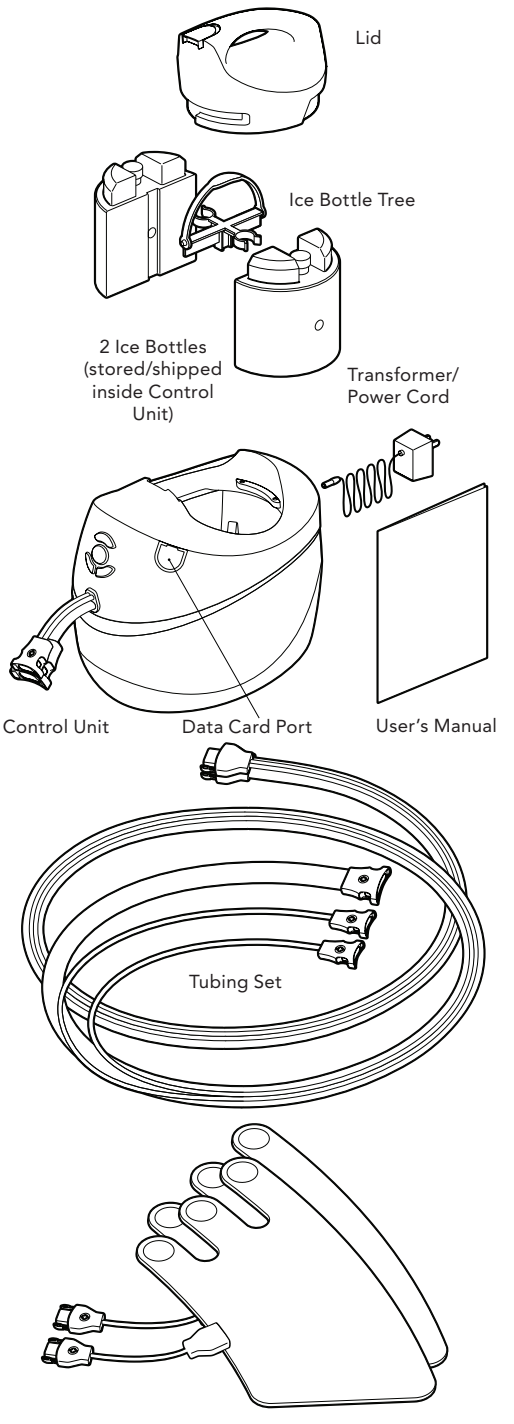
- Intermittent sequential compression therapy to prevent hospital-acquired venous thromboembolism.
- Intermittent dynamic compression therapy to reduce swelling.
- Controlled cold therapy to reduce pain and swelling.

Each of these separate treatment modalities is considered vital to effective post-operative rehabilitation and complication prevention. The range of benefits includes:

- A safe and effective system for both the practitioner and individual patient.
- A portable post-op therapy system that integrates vital preventative and rehabilitative modalities into one convenient, easy to use device.
- A variety of treatment pads which are comfortable, adjustable, and easy to apply to major joints and muscles.

Designed to provide a continuity of care from the hospital, surgery center, and clinic to self-treatment at home, the VPULSE makes complying with post-operative instructions easy.

Packing Contents



2 VPULSE Sequential Compression Therapy pads

Specifications

MODEL	VPULSE, C00001
PHYSICAL Size (approximately)	9.8" x 14.3" x 11.25" (249mm x 364mm x 286mm)
Weight (dry) Dual Tubing set	5 lbs. (2.27 kg) 10 ft. (2.4m)
CONTROLS	Keypad interface
THERMAL SYSTEM Operating limit Operating period	42°F minimum (5.5°C) Ice or frozen Ice Bottles will last for 2-6 hours
Circulating System Reservoir Capacity Reservoir Fluid Water Flow Rate	Submersible pump 1.2 gallons (4.4 liters) water 3.2 gph (12 lph) typical
PNEUMATIC SYSTEM Dynamic Compression peak pressure Sequential Compression peak pressure	 50mmHg ± 10% 60mmHg peak ± 10%
USER APPLIED PADS	
Thermal/Compression Pads C00003 VPULSE, Thermal/ Compression Pad, Knee C00004 VPULSE, Thermal/ Compression Pad, Shoulder	 TPU Polyether bladder, Polyurethane foam with 100% Polyester fabric lamination
Sequential/Compression Pads C00002 VPULSE with Sequential Compression Pad Set (2x)	 PVC plastic bladder, Polyurethane foam with 100% Polyester fabric lamination
ELECTRICAL SYSTEM Voltage Power Leakage Current	 12VDC, 100-240Vac, 50/60Hz 15W max 300µA max
OPERATING ENVIRONMENT Atmospheric Pressure Humidity Temperature	 707 to 760 mmHg 30% to 70% relative non-condensing 50°F – 104°F (10°C – 40°C)
TRANSPORT & STORAGE ENVIRONMENT Atmospheric Pressure Humidity Temperature	 179 to 760 mmHg 10% to 95% 32°F – 122°F (0°C – 50°C)
REGULATORY Classification Type of Equipment	 Class II Equipment Type BF

REGULATORY APPROVALS	IEC60601-1, 3rd edition, 2009: Standard for Medical Equipment Part 1: General Requirements for Safety. CAN/CSA-C22,2 no 60101-1-08 (R2008): Medical Electrical Equipment Part 1: General Requirements for Medical Electrical Equipment. VPULSE™ is intended for sale only in the US market. VPULSE™ and Healing Engineered™ are trademarks of Cothera, LLC. Patents Pending

Manufacturer's Warranty

Cothera warrants that the VPULSE (Product), if properly used, will be free from defects in material and workmanship for a period of 90 days after the date the VPULSE is purchased. If the VPULSE, which is the subject of this Limited Warranty, malfunctions during the warranty period for reasons covered by this Limited Warranty, Cothera, at its options, will:

- REPAIR the VPULSE or
- REPLACE the VPULSE at no charge with another VPULSE.

THIS LIMITED WARRANTY AND ANY IMPLIED WARRANTIES THAT MAY EXIST UNDER STATE LAW APPLY ONLY TO THE ORIGINAL END USER AND ARE NON-TRANSFERABLE.

Extent of Limited Warranty

This limited warranty does not cover damages due to external causes, including, without limitation, accident, usage not in accordance with Product User's Manual, misuse, neglect, alteration or repair.

How to Obtain Warranty Service

To obtain warranty service, call Cothera Customer Service at 1.855.558.7700 or go online to www.cothera.com. If the original end user qualifies for

warranty service from Cothera, a Returned Material Authorization (RMA) number will be issued. When returning the Product to Cothera, the RMA number must be indicated on the outside of the package. Cothera may not accept returned Product without an RMA number on the outside of the package. The original end-user must use the original packaging and assume the risk of damage or loss during shipping. Cothera may require written verification that the returner of the Product is the original end-user. The returned Product shall become property of Cothera upon receipt. Replacement Product is warranted under this written warranty and is subject to the same limitations and exclusions for the remainder of the original warranty period.

THIS WARRANTY IS NOT TRANSFERABLE.

Warranty Limitations and Exclusions

THESE WARRANTIES REPLACE ALL OTHER WARRANTIES, EXPRESS OR IMPLIED INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. COTHERA MAKES NO EXPRESS WARRANTIES BEYOND THOSE STATED HERE. COTHERA DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED INCLUDING, WITHOUT LIMITATION, IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

SOME JURISDICTIONS DO NOT ALLOW THE EXCLUSION OR LIMITATION OF IMPLIED WARRANTIES SO THIS LIMITATION MAY NOT APPLY. ALL EXPRESSED AND IMPLIED WARRANTIES ARE LIMITED IN DURATION TO THE LIMITED WARRANTY PERIOD.

Limitations of Liability

THE RESPONSIBILITY OF COTHERA UNDER THIS, OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, IS LIMITED TO REPAIR OR REPLACEMENT, AS SET FORTH ABOVE. THESE REMEDIES ARE THE SOLE AND EXCLUSIVE REMEDIES FOR ANY BREACH OF WARRANTY. COTHERA IS NOT RESPONSIBLE FOR DIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES RESULTING FROM ANY BREACH OF WARRANTY OR UNDER ANY OTHER LEGAL THEORY INCLUDING, BUT NOT LIMITED TO, LOST PROFITS, DOWNTIME, GOODWILL, AND DAMAGE TO OR REPLACEMENT OF EQUIPMENT AND PROPERTY. SOME JURISDICTIONS DO NOT ALLOW THE EXCLUSION OR LIMITATION OF INCIDENTAL OR CONSEQUENTIAL DAMAGES, SO THE ABOVE LIMITATIONS OR EXCLUSIONS MAY NOT APPLY. THIS LIMITED WARRANTY GIVES THE ORIGINAL END-USER SPECIFIC RIGHTS. THE ORIGINAL END-USER MAY ALSO HAVE OTHER RIGHTS THAT VARY FROM JURISDICTION TO JURISDICTION.

Notes, Cautions & Warnings

This section is used to highlight certain operating procedures and recommendations. A Note indicates a special procedure, an exception to normal operation or something else of specific interest to the reader. Notes are preceded by the word “Note” in italics.

The Caution or Warning symbol precedes an operational step that could damage the instrument if the patient does not take certain precautions. Cautions or Warnings are located in the main text, are preceded by a Caution or Warning statement and are accompanied by this symbol in the left margin.

Caution: risk of electric shock.

Symbol ISO 7010-M002: refer to the User’s Manual for instructions for product usage.

Important Safety Instructions / Read all instructions before using.

This equipment has been tested and found to comply with the limits for medical devices according to the IEC60601-1.

When using an electrical appliance, especially when children are present, basic safety precautions should always be followed.

Electromagnetic Interference

This device has been tested and found to comply with the limits for Medical Devices according to IEC60601-1-2: 2007. These limits are designed to provide reasonable protection against harmful interference in typical medical installations. This equipment generates and radiates radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. There is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user can try to correct the interference by one or more of the following measures:

Reorient or relocate the receiving device.

Increase the physical separation between the equipment and other device(s).

Connect the equipment into an outlet or circuit different from the one where the other device(s) are connected.

Safety Symbols & Warnings

DANGER – TO REDUCE THE RISK OF ELECTRICAL SHOCK, DO NOT DISASSEMBLE THE UNIT. REFER SERVICING TO THE MANUFACTURER:

1. Always unplug this appliance from the electrical outlet immediately after using and before cleaning.

2. DO NOT use while bathing or in a shower.

3. DO NOT place or store appliance where it can fall or be pulled into a tub or sink. DO NOT place in or drop into water or other liquid.

4. DO NOT reach for a product that has fallen into water. Unplug immediately.

As with all prescription medical devices, failure to follow product instructions or adjusting setting and performing therapy applications without the express direction and/or supervision of your trained health care provider may lead to improper product performance and the potential for serious injury. For medical questions, please consult your health care provider.

℞ ONLY This device is offered for sale or by order of a physician or other health care provider. Use only as prescribed.

A health care provider is responsible for providing use instruction to the patient and others involved in the care of the patient. A licensed health care provider must specify treatment parameters regarding the frequency and duration of cold and compression applications and breaks, how and when to inspect the skin, and total length of treatment.

A healthcare provider must provide adequate use instructions to a patient if the patient is to use product for self-treatment.

The device should never be left unattended when plugged in. Unplug from outlet when not in use and before putting on or taking off parts.

Warning: No modification of this equipment is allowed.

Only use the power supply provided with the unit. Failure to do this could damage the unit, power supply, and/or create a potential injury to the patient. Please contact Cothera Customer Service if a replacement wall adapter is required.

DO NOT use around flammable materials.

It is important to observe patient's skin condition during use. If redness of the skin develops, numbness, pain or a change in skin sensitivity occurs, discontinue the use of this product immediately and contact your health care provider.

Be aware of any nerve irritation and/or muscular reaction that are associated with skin sensitivity and irritation. If observed, discontinue therapy until the cause is determined.

Special attention should be taken if the patient received a nerve blocking agent. Please consult your health care provider for proper product use in this instance.

The VPULSE pads are supplied non-sterile. DO NOT sterilize these pads. Doing so may compromise the functionality of the pad(s) and may result in possible patient injury.

All VPULSE pads are intended for single patient use and NOT intended for reuse or to be washed or cleaned. Doing so may compromise the functionality of the pad(s) and may result in possible patient injury.

DO NOT wrap the therapy pads as to restrict blood or fluid flow. Regularly check the therapy area.

DO NOT lay on top of the pad connectors. Doing so may result in patient injury.

DO NOT use pins or sharp objects to secure the therapy pads or hoses. Doing so may damage the system and compromise function.

DO NOT kink or sharply bend the tubing set. Doing so may demage the system and compromise the function.

Close supervision is necessary when this appliance is used by, on or near children, unconscious or incapacitated patients and those with poor circulation.

Use this appliance only for its intended use as described in this manual. DO NOT use attachments not recommended by the manufacturer. DO NOT use attachments from other manufacturers. Connecting parts not supplied by Cothera will void the warranty and may cause damage to the system and potential injury to the patient.

Never operate this appliance if it has a damaged cord, plug or wall adapter, if it is not working properly, if it has been dropped or damaged, or dropped into water.

Medical Device Safety Symbol IEC 60417-5333: Type BF Applied part complying with IEC 60601-1 to provide protection against electric shock. The part of the device in contact with the patient is floating from earth ground.

IPX3 Protected against spraying water.

Medical Device Symbol IEC 60417-5031: The product operates from direct current.

Medical Device Symbol IEC 60417-5172: Class II Equipment.

Medical Device Symbol IEC 60417-5570: Unlocking, Handle.

Medical Device Symbol IEC 60417-5569: Locking, Handle.

Minimum water reservoir fill line. Step 1 of filling the water reservoir.

Maximum water reservoir fill line. Step 2 of filling the water reservoir. Note that either ice or the VPULSE Ice Bottles can be used for cold therapy.

Cold therapy enable function.

►/■ Start /Stop the therapy session.

Dynamic compression therapy enable function.

Sequential compression therapy enable function.

Ensure the handle of the device is properly installed and fully engaged prior to carrying the system. For proper use, please reference the handle locking and unlocking icons.

Use proper precautions in carrying the device to avoid injury.

DO NOT carry this appliance by the supply cord or use the supply cord as a handle.

Keep the cord away from heated surfaces.

When setting up the system, route the supply cord and tubing set to avoid tripping and to encourage ease of walking around the device.

DO NOT carry this appliance by the tubing set or use the tubing set as a handle.

Keep the tubing set away from heated surfaces.

Never operate the appliance without the handle, the tubing set, and the pad(s) completely connected.

Never operate the appliance with any foreign objects (other than ice or Ice Bottles provided) in the water reservoir.

Never drop or insert any object into any opening.

To disconnect, stop operation (■), and then remove plug from outlet.

Use cooling surfaces carefully. DO NOT use over insensitive skin areas or in the presence of poor circulation. The unattended use of cooling by children or incapacitated persons may be dangerous and is not recommended. Consult your health care provider to discuss any specific contraindications for use.

DO NOT stand on or in the appliance.

DO NOT use while sleeping or drowsy.

DO NOT place the appliance or operate the appliance while it is on a surface more than 1 foot above the floor.

Unplug this product before filling or cleaning. Fill with water and ice or water and Ice Bottles provided by Cothera only. DO NOT use any Ice Bottles other than those provided by Cothera.

Fill Ice Bottles with water only.

DO NOT overfill.

DO NOT operate without water.

DO NOT operate with hot water.

DO NOT place the tubing set, power cord or use any pad around the neck.

DO NOT place a cast over a pad. Casting over the pad & tubing set may restrict necessary air circulation and proper operation.

VPULSE does not contain natural rubber latex, nor is natural rubber latex added as part of the production process.

Cothera does not have an authorized service center. However, if this device is still under warranty, contact the Cothera Consumer Service Department at 1.855.558.7700 or reach us online at www.cothera.com to return this device.

Follow local governing ordinances and recycling plans regarding disposal or recycling of device components. If unclear, please refer to Cothera for proper disposition of this product.

Manufactured by COTHERA LLC.

Indications & Contraindications

Patients with the following conditions should use the VPULSE under direct supervision of a health care provider:

- Extremities not sensitive to pain
- Individuals with extremely low blood pressure
- Individuals with Raynaud's Disease
- Hypersensitivity to cold
- Children
- Individuals with diabetes

General Indications for Cold Therapy

General reasons for using cold therapy are:

- First aid after trauma
- Relief of pain
- Aid in control of bleeding
- Prevention or reduction of swelling of traumatic origin
- Prevention or reduction of inflammation
- Decrease of muscle spasms
- Temporary reduction of muscle tightness and/or stiffness

Cold is preferred during the initial treatment of injury where swelling and redness exist.

Contraindications for Cold Therapy

Patients should be aware of situations where cold therapy is not recommended for use.

This includes patients with sensitivity to cold:

- Diabetes
- Hives caused by decreased temperature
- Blood protein problems caused by decreased temperature (Cryoglobulinemia)
- Disorder causing discoloration of the fingers, toes, and other areas (Raynaud's syndrome)
- Elevated hemoglobin levels in urine caused by decreased temperature (Proximal cold hemoglobinuria)
- Diseases leading to narrowing of blood vessels (Vasospastic disease)
- Extreme sensitivity to cold
- Lowered blood circulation in the affected extremity

Patients should be careful when applying cold therapy over open sores and scrapes. These areas should be cleaned and bandaged.

Regularly check the skin where the pad is applied. Stop use if continued numbness, skin discoloration, or blisters are present. Please contact your healthcare professional before:

- Using this system
- Using this system for extended periods of time.

General Indications for Intermittent Pneumatic Compression Therapy

General reasons for using Intermittent Pneumatic Compression Therapy are:

- Reduction of swelling associated with injuries such as burns, postoperative swelling, and sprains
- Decrease the risk of blood clots in leg veins;
- Aids the blood flow back to the heart;
- Treats and assists in the healing of wounds, reduces wound healing time, enhances blood flow, reduces pressure on nerves, blood vessels, and muscles, reduces swelling, and reduces the need for blood thinning medications.

Patients with the following conditions should use the VPULSE only by prescription and under direct supervision of a physician:

- Arms and legs not sensitive to pain
- Extremely low blood pressure
- Individuals with disorders causing discoloration of the fingers, toes, and other areas
- Extreme sensitivity to cold
- Children
- Diabetics

Contraindications for Intermittent Pneumatic Compression Therapy

Patients with the following conditions should not use the VPULSE:

- Congestive heart failure
- Deep vein thrombosis or blockage of arteries in lungs
- Deep blood clots in veins
- Inflammation of veins
- Fluid buildup in the lungs
- Blockage of arteries in the lungs
- Inflammation of the veins

- Reduced heart function
- Blood flow problems in the arteries
- Bacterial infection of the skin
- Cancer in the affected extremity
- Uncontrolled muscle tightness and/or stiffness
- Inflammatory skin diseases or infection
- Venous or arterial occlusive disease
- Disorder causing discoloration of the fingers, toes, and other areas
- Poor circulation in extremities
- Increased sensitivity to cold
- Situations where increased blood circulation is undesirable
- Gangrene
- Recent skin graft
- Fracture of the affected limb
- Extremities that are not sensitive to pain

System Operation

The VPULSE consists of a control unit, tubing set and a family of single-patient application pads. The pads are applied to the body to deliver three different and important therapeutic treatments. There are two types of pads to deliver three different therapies:

- The patient can apply (1) or (2) sequential compression therapy pad(s) to the calves for preventative treatment of venous thromboembolism.

  And/or

- The patient can apply (1) thermal-compression pad to a specific body part such as the knee or shoulder for cold therapy and/or dynamic compression therapy to manage pain and swelling for post-operative recovery.

The control unit contains:
- an air pump and reservoir for inflating portions of each pad;
- a water pump and patient-filled ice water container for circulating water into the thermal-compression pad; and
- supporting controls to deliver and monitor the treatment therapies.

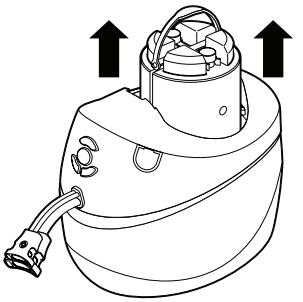
Once power is connected to the VPULSE, it is powered ON. The patient can then select which therapies to use and start the treatment session. Pressurized air and/or cooled water is circulated through the tubing set from the control unit to the pads. The air pressure is cycled until the therapy session is stopped by the patient.

When using this system, please check the skin where the pads are applied. Discontinue use if continued numbness, skin discoloration, blisters, etc. are present. Please refer to your health care provider for treatment parameters prior to applying this system and/or using the system for extended periods of time.

⚠ **DO NOT operate without water in the system. Doing so may damage your system and void the product warranty.**

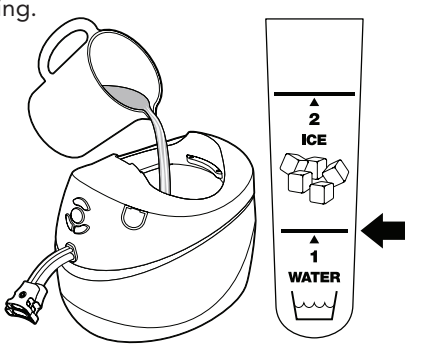
Operating Instructions

Every VPULSE is quality tested before being sold. When un-packing your new system, it is normal to find moisture in the VPULSE water reservoir due to the testing.



1

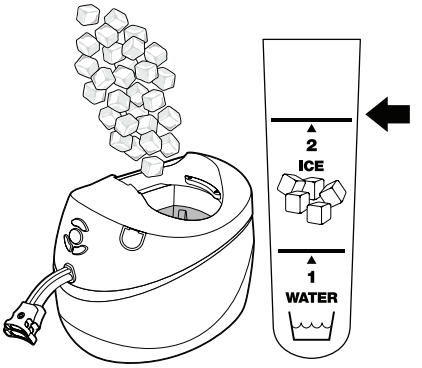
Remove the two Ice Bottles from the Control Unit.



2

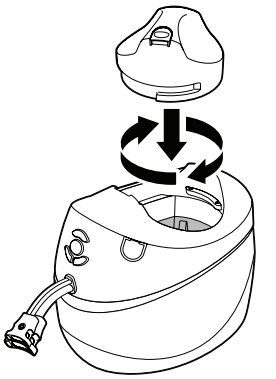
Pour cold water into the Control Unit to the “WATER” level indication on the inside of the container.

Using the System with ice and water



3

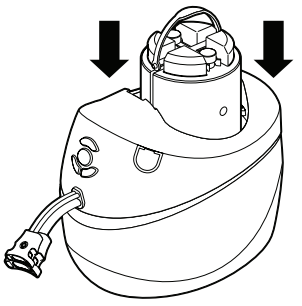
Pour ice water into the Control Unit until even with the “ICE” level indication on the inside of the container.



4

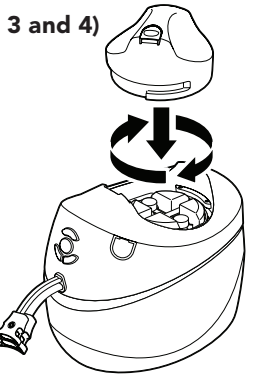
Place the lid onto the Control Unit and turn clockwise until the handle clicks into position.

When using the System with Ice Bottles and water (omit steps 3 and 4)



5

Place the two Ice Bottles into the Control Unit.



6

Place the lid onto the Control Unit and turn clockwise until the handle clicks into position.

Guide to using your Ice Bottles

If your VPULSE includes the Ice Bottle pair or you purchased them as an accessory, please follow the below instructions.

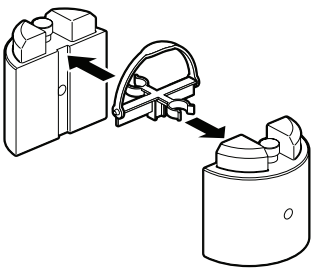
1. Fill the Ice Bottle with tap water. Freeze the filled Ice Bottle for a minimum of 6 hours in any household freezer to ensure maximum cold therapy.

The time the Ice Bottle will stay frozen is approximately 2 to 6 hours. Use additional Ice Bottles for longer treatment.

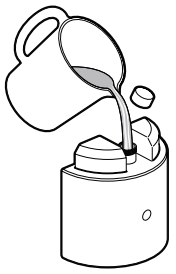
⚠ To avoid skin irritation or cold burn, DO NOT hold frozen Ice Bottles for an extended period. DO NOT use the Ice Bottles directly on skin contact for therapeutic purposes.

2. Place the frozen Ice Bottle into the reservoir. Make sure water us already in the VPULSE Unit up to the water line. For longer duration of sustained cold water temperature, add ice in addition to the Ice Bottle to the water reservoir (as desired). Only fill the Ice Bottles with water.

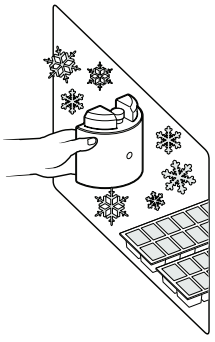
To order additional Ice Bottles please go to www.cothera.com or call 1.855.558.7700



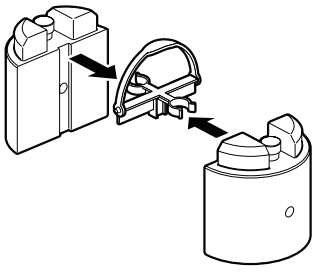
a) Detach frozen Ice Bottles from the Holder Tree.



b) Fill Ice Bottles with water



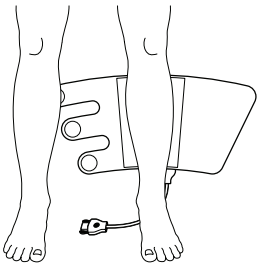
c) Freeze Ice Bottles



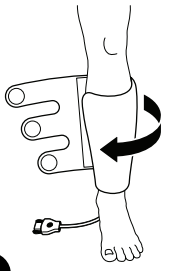
d) Attach frozen Ice Bottles to the Holder Tree.

⚠ APPLY THERAPY PADS ONLY TO BODY PART INDICATED FOR THE ASSOCIATED PAD. FAILURE TO FOLLOW THE PRODUCT INSTRUCTIONS MAY LEAD TO IMPROPER PRODUCT PERFORMANCE AND THE POTENTIAL FOR SERIOUS INJURY.

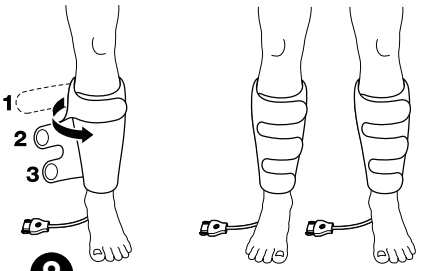
Apply the Sequential Compression Therapy pads to the patient's calves



7 Center the pad behind the patient's calf.



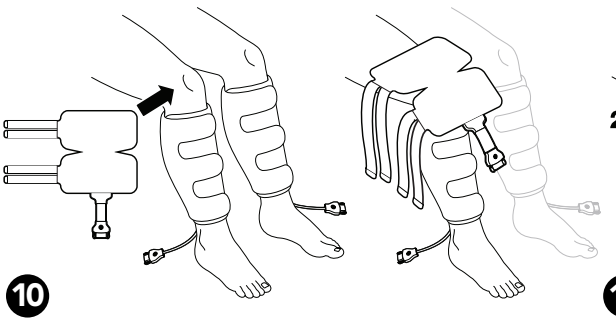
8 Wrap one side of the pad, as shown, around the front of the patient's leg.



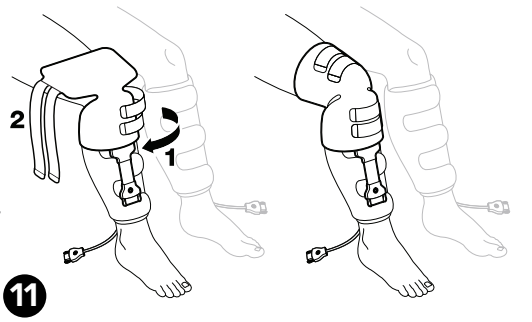
9 Secure by wrapping the 3 "fingers" in the order shown around to the front. Apply pads to both calves. Adjust so snug. Do not over tighten.

Apply 1 Cold-Dynamic Compression pad to the appropriate body part (Example: knee)

(Refer to the shoulder pad or other available pads for the application instructions for each pad.)

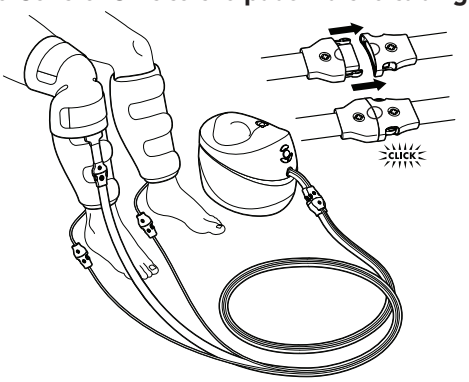


10 Center the pad over the patient's knee with the connector pointing down.

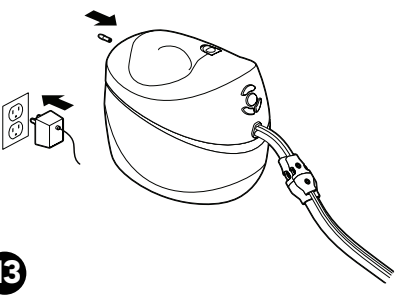


11 Wrap straps around the knee to secure the pad.

Attach the Control Unit to the pads via the tubing set



12 Attach the Control Unit to the pads using the connectors as shown. The connectors make a "click" sound when fastened properly.



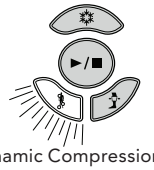
13 Plug the Control Unit into a grounded AC outlet.

Starting a treatment session, selecting desired therapies, and silencing an alarm

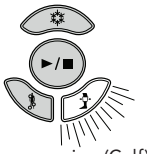
Use the Start/Stop button to start, change, pause or stop therapies.

Start/Stop

Cold Only



Dynamic Compression Only

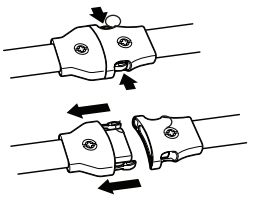


Sequential Compression (Calf) Pad Only

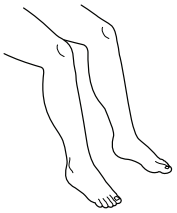
Press the button of the desired therapy or combination of therapies. The buttons selected will be illuminated. Push the Start/Stop button to begin.

To Pause or Discontinue Use

Press the Start/Stop button to stop.



Disconnect by depressing the side buttons of the connectors.



Remove the Sequential Compression Therapy pads and Thermal-Compression pad.

Alarms

When an alarm occurs, the system will stop the therapy session, sound an audible alert and illuminate in RED the function key of the alarm area.

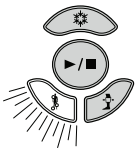
To stop an alarm, press the function key that is flashing.

Cold Therapy may alarm if:

- Too low or too high a therapy temperature may be detected by the system.

To resolve:

- Check the tube connection at the Control Unit and at the cold-compression pad.
- Check water levels.
- Check for appropriate ice or water level
- Refer to previous steps on proper filling of the fluid container.

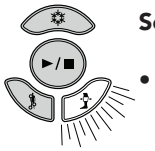


Dynamic Compression may alarm if:

- The time to inflate the pad is too short or too long.

To resolve:

- Check the tube connection at the Control Unit and at the cold-compression pad.
- Make sure the cold-compression therapy pads are properly applied to the body and connected properly.



Sequential Compression may alarm if:

- The time to inflate the pad is too short or too long.

To resolve:

- Make sure the sequential compression therapy pads are properly applied to the calf and connected properly.

Alerts

Flashing GREEN

To resolve:

- The Stop/Start button will flash when the system is initializing. This may occur after power disruption or after the system was improperly shut down.

Dynamic Compression and Sequential Compression keys Solid RED

To resolve:

- The SD card is not properly installed, the card is full or faulty. Remove or reinstall the card. If this condition persists contact Customer Service.
- **Cold Therapy is still active during this condition.**

Dynamic Compression VIOLET and Sequential Compression RED

To resolve:

- The air pump is not achieving pressure, contact Customer Service.

Troubleshooting

Frequently asked questions in troubleshooting the VPULSE:

1. What should I do if the VPULSE does not seem to get cold?

- Check the inside and outside of the water reservoir for cracks, punctures or other signs of damage. If damage is noted, please contact Customer Service at Cothera, 1.855.558.7700.
- Make sure that the water reservoir is properly filled with water.

DO NOT operate the system with a water reservoir **not filled with water** or not filled to the MINIMUM fill line, before ice or Ice Bottles are added.

- DO NOT operate the system with a water reservoir filled with water above the MAXIMUM fill line, or with a tubing set not properly connected.
- Check that enough ice is added to the water reservoir and that the tubing is not kinked.
- Check the power connection.
- Refer to Customer Service at Cothera, 1.855.558.7700 if these actions are ineffective.

2. What should I do if the tubing set does not connect to the VPULSE or pad?

- Check the tubing set and connectors for cracks, punctures or other signs of damage. If damage is noted, contact Customer Service at Cothera, 1.855.558.7700.
- Make sure the correct connectors are mating. Check the color and number of connections.
- Make sure no foreign objects are blocking the fluid connectors.
- Refer to Customer Service at Cothera, 1.855.558.7700 if these actions are ineffective.

3. What should I do if the system does not turn on?

- Check wall adapter power connection at the wall.
- Check the outlet to ensure it is properly powered.
- Check wall adapter is connected at back of the Control Unit.
- Make sure no foreign objects are blocking the fluid connectors.
- Check that the front panel keys illuminate when pressed.
- Check that the Start/Stop key (►/■) illuminates GREEN when pressed.
- Refer to Customer Service at Cothera, 1.855.558.7700 if these actions are ineffective.

4. What should I do if the system is not pumping water through the pad?

- Check power connection.
- Check that the tubing set is properly connected.
- Check that the pads are properly connected.
- Check that the water reservoir is properly filled with cold water.
- Check that the Cold Therapy button has been selected and the function illuminates WHITE.
- Check that the Start/Stop key (►/■) illuminates GREEN when pressed.
- Check that the tubing is not kinked.
- Start the system to ensure that the water is flowing into the water reservoir. A return stream is visible inside water reservoir.
- Refer to Customer Service at Cothera, 1.855.558.7700 if these actions are ineffective.

5. What should I do if the system is not pumping any air through the pad?

- Check power connection.
- Check that the tubing set is properly connected.
- Check that the pads are properly connected.
- Check that the front panel keys illuminate when pressed and that a compression therapy is selected. If the compression keys are both continuously illuminated RED and VIOLET the air pump might not be providing sufficient pressure.
- If compression keys are both continuously illuminated RED, the DATA card may not be installed, the card may be full, or experiencing a problem. Open the DATA door and reinstall the DATA card.
- Check that the Start/Stop key (►/■) illuminates GREEN when pressed.
- Check that pad is inflating.
- Check the dynamic or sequential therapy mode is enabled.
- Refer to Customer Service at Cothera, 1.855.558.7700 if these actions are ineffective.

Cleaning your VPULSE

To clean your VPULSE, please follow these simple steps:

1. Remove electrical cord.
2. Fill the empty water reservoir to the MAX fill line with fresh, room temperature water. DO NOT USE ANY CLEANING SOLUTIONS IN THE WATER RESERVOIR AS THESE SOLUTIONS COULD DAMAGE THE WATER PUMP AND THERAPY PADS.
3. Replace the handle and connect power. Connect all pads and enable all functions.
4. Operate the system for 10 minutes.
5. Empty the water reservoir.
6. Repeat these actions periodically.

Please use only the following cleaning agents when cleaning the outside of your VPULSE system: warm water with mild detergent, Lysol©, 70% isopropyl alcohol, Cidex©, or 10% bleach solution.

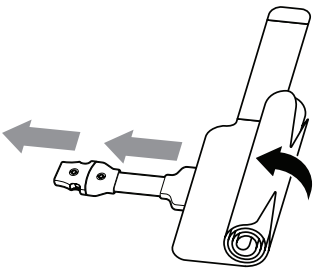
Patients should not use cleaning or decontamination methods different from those recommended by the manufacturer without first checking with the manufacturer that the proposed methods will not damage the equipment.

Care & Maintenance of Your VPULSE

- DO NOT store the pad in its shipping bag. The shipping bag may trap the moisture remaining in the pad.
- Store the VPULSE unit in a safe, cool and dry place when not in use.
- Ensure the water reservoir is empty of water and dry to avoid bacterial growth and contamination.
- Wipe down the device with a soft, damp cloth. DO NOT use abrasive cleaner. NEVER immerse the unit into any liquid.
- Keep away from all solvents and harsh detergents. Please refer to cleaning instructions prior to cleaning your VPULSE.
- DO NOT attempt to repair the VPULSE. There are no patient-serviceable parts. Repair of the system by an unauthorized person may void the product warranty.
- To store, disconnect the electrical cord, the tubing set and the pad.

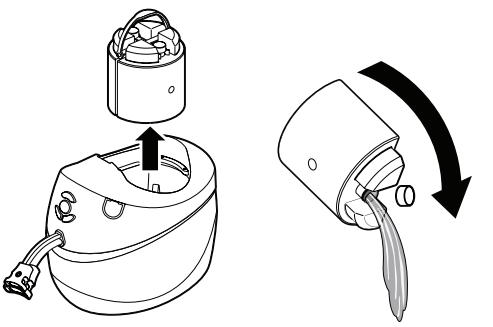
Lysol© is a registered trademark of Reckitt Benckiser Inc.
Cidex© is a registered trademark of Johnson & Johnson Corp.

Storage



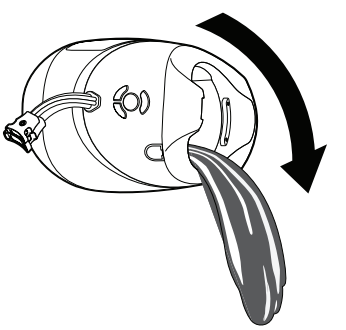
1

Remove water from the Thermal-Compression pad by rolling the pad up while still connected and squeezing the water back into the Control Unit.



2

Remove the Ice Bottles from the unit. Separate the bottles and pour the water out, air dry.



3

Dump the water out of the side Control Unit so that the control buttons and other electrical components stay dry. When empty, let the unit "air dry" completely.

For long term storage, please use the shipping materials and container supplied with the VPULSE.

Catalog Items

To order additional items from Cothera, please refer to the following items:

Catalog Item	Description
C00002	**VPULSE with Sequential Compression Pad set (2x)**
C00003	**VPULSE Thermal/Compression Pad, Large Knee**
C00003-NL	**VPULSE Thermal/Compression Pad, Large Knee, No Liner**
C00004	**VPULSE Thermal/Compression Pad, Shoulder**
C00005	**VPULSE Thermal/Compression Pad, Foot/Ankle**
C00013	**VPULSE Thermal/Compression Pad, Hip**
C00013-NL	**VPULSE Thermal/Compression Pad, Hip, No Liner**
C00016	**VPULSE Thermal/Compression Pad, Universal**
C00017	**VPULSE Thermal/Compression Pad, Standard Knee**
C00020	**VPULSE Thermal/Compression Pad, Universal Back**
C00020-NL	**VPULSE Thermal/Compression Pad, Universal Back, No Liner**
C000XX-NL	Several pads are available without a liner and are indicated by -NL at the end of the code e.g. C00003-NL (Large Knee, No Liner)
C000XX-XX	Systems can be ordered with pads. When ordering please use the last two digits of your system to indicate the pad. Example C00002-03 = VPULSE with Sequential Compression Pad set (2x), includes Thermal/Compression Pad, Large Knee
	Accessories
C00006	**VPULSE Sequential Compression Pad set (2x)**
C00007	**VPULSE Spare Ice Bottle Set**
C00008	**VPULSE 12VDC-24W Wall Adapter**
C00009	**VPULSE Thermal/Compression Tubing Set**
C00010	**VPULSE Sequential Compression Tubing Set**
C00011	**VPULSE Handle, Replacement**
C00012	**VPULSE Users Manual**
C00014	**VPULSE Product Specification Brochure**
C00015	**VPULSE Carrying Bag**
C00018	**VPULSE Complete Tubing set**
C00024	**VPULSE Power Extension Cable**

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